



Dkt. 58332/JPW/EMW/APE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Nicole Suciu-Foca  
Serial No.: 09/333,809 Examiner: Not Yet Known  
Filed : June 15, 1999  
For : GENERATION OF ANTIGEN SPECIFIC T SUPPRESSOR CELLS  
FOR TREATMENT OF REJECTION

1185 Avenue of the Americas  
New York, New York 10036  
August 9, 1999

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

Applicant submits herewith an Information Disclosure Statement under 37 C.F.R. §1.56.

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicant directs the Examiner's attention to the following disclosures:

1. Banchereau, J., Steinman, R. M. (1998) "Dendritic cells and the control of immunity," *Nature* 392:245-252. (Exhibit 1).
2. Barker, T. D., Weissman, D., Daucher, J. A., Roche, K. M., and Fauci, A. S. (1996) "Identification of multiple and distinct CD8+ T cell suppressor activities: dichotomy between infected and uninfected individuals, evolution with progression of disease and sensitivity to gamma radiation," *Clin. Immunol.* 156:4476-4483. (Exhibit 3).
3. Bennett, S. R. M., Carbone, F. R., Karamalis, F., Flavell, R. A., Miller, J., and Heath, W. R. (1998) "Help for cytotoxic-T-cell responses is mediated by CD40 signaling," *Nature* 393:478-480. (Exhibit 2).
4. Ciubotariu, R., Colovai, A. I., Pennesi, G., Liu, Z., Smith,

- D., Berlocco, P., Cortesini, R., Suciu-Foca, N. (1998) "Specific suppression of human CD4+ Th cell responses to pig MHC antigens by CD8+CD28- regulatory T cells," *J. Immunol.* 161(10): 5193-5202. (Exhibit 4).
5. Damle, N. K., Mohagheghpour, N., Hansen, J. A., and Engleman, E. G. (1993) "Alloantigen-specific cytotoxic and suppressor T lymphocytes are derived from phenotypically distinct precursors," *J. Immunol.* 151:2296-2300. (Exhibit 5).
  6. Groux, H., O'Garra, A., Bigler, M., Rouleau, M., Antonenko, S., de Vries, J. E., and Roncarolo, M. G. (1997) "A CD4+ T-cell subset inhibits antigen-specific T-cell responses and prevents colitis," *Nature* 389:737-742. (Exhibit 6).
  7. Jiang, S., Tugulea, S., Pennesi, G., Liu, Z., Mulder, A., Lederman, S., Harris, P., Cortesini, R. and Suciu-Foca, N. (1998) "Induction of MHC-class I restricted human suppressor T cells by peptide priming *in vitro*," *Hum. Immunol.* 59:690-699. (Exhibit 7).
  8. Lanier, L. L., O'Fallon, S., Somoza, C., Philips, J. H., Linsey, P. S., Okumura, K., Ito, D. and Azuma, M. (1995) "CD80 (B7) and CD86 (B70) provide similar costimulatory signals for T cell proliferation, cytokine production and generation of CTL," *J. Immunol.* 154:97-105. (Exhibit 8).
  9. Liu, Z., Tugulea, S., Cortesini, R., Suciu-Foca, N. (1998) "Specific suppression of T helper alloreactivity by allo-MHC class I-restricted CD8+CD28- T cells," *Int. Immunol.* 10(6):775-783. (Exhibit 9).
  10. Lombardi, G., Sidhu, S., Batchelor, R., Lechler, R. (1994) "Anergic T cells as suppressor cells *in vitro*," *Science*

264:1587-1589. (Exhibit 10).

11. Noble, A., Zhao, Z., and Cantor, H. (1998) "Supression of immune responses by CD8 cells. II. Qa-1 on activated B cells stimulates CD8 cell supression of T Helper 2 responses," *J. Immunol.* 160:566-571. (Exhibit 11).
12. Qin, S., Cobbold, S. P., Pope, H., Elliott, J., Kioussis, D., Davies, J., and Waldmann, H. (1993) "'Infectious' transplantation tolerance," *Science* 259:974-977. (Exhibit 12).
13. Ridge, J. P., Di Rosa, F., and Matzinger, P. (1998) "A conditioned dendritic cell can be a temporal bridge between a CD4+ T-Helper and a T-Killer cell," *Nature* 393:474-478. (Exhibit 13).
14. Schoenberger, S. P., Toes, R. E. M., Van Der Voort, E. I. H., Offringa, R., and Melief, C. J. M., (1998) "T-Cell help for cytotoxic T lymphocytes is mediated by CD40-CD40L interactions," *Nature* 393:480-483. (Exhibit 14).
15. Schwartz, R. H. (1992) "Costimulation of T lymphocytes: The role of CD28, CTLA-4, and B7/BB1 in interleuken-2 production and immunotherapy," *Cell* 71:1065-1068. (Exhibit 15).
16. Tan, P., Anasetti, C., Hansen, J. A., Melrose, J., Brunvand, M., Bradshaw, J., Ledbetter, J. A., and Linsey, P. S. (1993) "Induction of alloantigen-specific hyporesponsiveness in human T lymphocytes by blocking interaction of CD28 with its natural ligand B7/BB1," *J. Exp. Med.* 177:165-173. (Exhibit 16).
17. Yang, Y., Wilson, J. M. (1996) "CD40 ligand-dependent T

Applicant: Nicole Suciu-Foca  
Serial No.: 09/333,809  
Filed: June 15, 1999  
Page 4

cell activation: Requirement of B7-CD28 signaling through CD40," *Science* 273:1862-1864. (Exhibit 17).

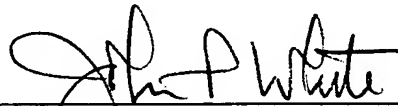
Each of the above-listed references is listed again on the accompanying PTO Form 1449 (Exhibit A), and copies of references 1-17 are attached hereto as Exhibits 1-17, respectively.

Applicants request that the Examiner review the references and make them of record in the subject application.

If a telephone conference would be of assistance in advancing the prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone at the number provided below.


No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

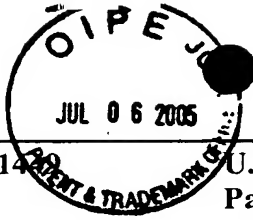


John P. White  
Registration No. 28,678  
Attorney for the Applicant  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, New York 10036  
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:  
Assistant Commissioner for Patents,  
Washington, D.C. 20231.

 8/9/99  
John P. White Date  
Reg. No. 28,678

**\*EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Form PTO-1429 <b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 58332/JPW/EMW/APE	Serial No. 09/333,809
	Applicant Nicole Suciu-Foca		
	Filing Date June 15, 1999	Group Art Unit Unknown	

U.S. PATENT DOCUMENTS													
Examiner Initial		Document Number							Date	Name	Class	Subclass	Filing Date if Appropriate

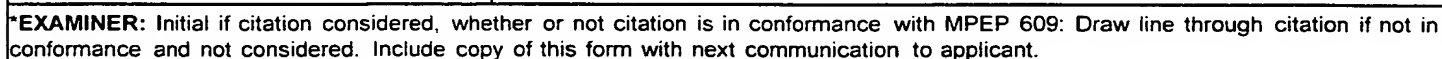
FOREIGN PATENT DOCUMENTS															
		Document Number								Date	Country	Class	Subclass	Translation	
														Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)									
		Barker, T. D., Weisman, D., Daucher, J. A., Roche, K. M., and Fauci, A. S. (1996)							
		"Identification of multiple and distinct CD8+ T cell supressor activities: Dichotomy							
		between infected and uninfected individuals, evolution with progression of disease and							
		sensitivity to gamma radiation," <i>J. Immunol.</i> 156:4476-4483. (Exhibit 3).							
		Ciubotariu, R., Colovai, A. I., Pennesi, G., Liu, Z., Smith, D., Berlocco, P., Cortesini, R.,							
		Suciu-Foca, N. (1998) "Specific supression of human CD4+ Th cell responses to pig							

EXAMINER	DATE CONSIDERED
----------	-----------------

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**\*EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.







**JUL 06 2005**

**Atty. Docket No.**  
**58332/JPW/EMW/APE**

**Serial No.**  
**09/333,809**

**Applicant**  
**Nicole Suci-Foca**

**Filing Date**  
**June 15, 1999**

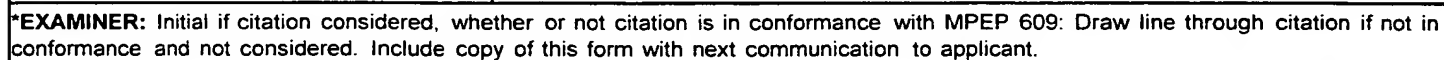
**Group Art Unit**  
**Unknown**

[illegible][illegible]

		suppressor T cells by peptide priming in vitro. <i>Hum. Immunol.</i> 59:690-699. (Exhibit 7).
		Lanier, L. L., O'Fallon, S., Somoza, C., Philips, J. H., Linsey, P. S., Okumura, K., Ito, D., and Azuma, M. (1995) "CD80 (B7) and CD86 (B70) provide similar costimulatory signals for T cell proliferation, cytokine production and generation of CTL," <i>J. Immunol.</i> 154:97-105. (Exhibit 8)

**DATE CONSIDERED**

**\*EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.





**Atty. Docket No.**  
**58332/JPW/EMW/APE**

Serial No.  
09/333,809

**Applicant**  
**Nicole Suci-Foca**

**Filing Date**  
**June 15, 1999**

**Group Art Unit**  
**Unknown**

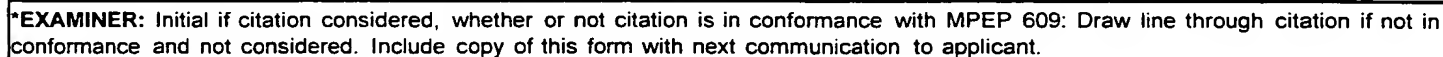
[illegible][illegible]

	Noble, A., Zhao, Z., and Cantor, H. (1998) "Supression of immune responses by CD8 cells. II. Qa-1 on activated B cells stimulates CD8 cell suppression of T helper 2 Responses," <i>J. Immunol.</i> <b>160</b> :556-571. ( <b>Exhibit 11</b> ).
	Qin, S., Cobbold, S. P., Pope, H., Elliott, J., Kioussis, D., Davies, J., and Waldman, H. (1993) "'Infectious' transplantation tolerance," <i>Science</i> <b>259</b> :974-977. ( <b>Exhibit 12</b> ).

**EXAMINER**

DATE CONSIDERED

\***EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



\***EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**\*EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.